REMARKS

Initially Applicants thank the Examiner for withdrawing prior rejections of record. Applicants respectfully request reconsideration and withdrawal of the pending rejections for the reasons set forth herein below.

I. STATUS OF THE PENDING CLAIMS

Claims 1, 4-5, 9, and 11-24, 27-40 are pending in this Application. Claim 12-23, 27-39 are withdrawn. Claim 2-3, 6-8, 10, 25-26 is canceled. Claims 1, 9, 24, and 40 are amended. Claims 1, 4-5, 9, 11, 24 and 40 stand rejected. The Examiner has maintained the withdrawal of claims 27-39. Applicants disagree with the Examiner's conclusion. Applicants reserve the right to file a divisional application directed to the withdrawal claims.

II. OBJECTION TO CLAIM 9

The Examiner has objected to claim 9, alleging that the phrase " and wherein the composition does not include an antagonist of the water soluble compound capable of abuse" is repetitive. Applicants have removed the recitation at issue. Therefore, the objection of claim 9 should be withdrawn.

III. REJECTION OF CLAIMS UNDER 35 U.S.C. § 112 FIRST PARAGRAPH, THE NEW MATTER REJECTION, IS IMPROPER

The Examiner has rejected claims 1, 4-5, 7, 9, 11, 24 and 40 for failing to comply with the written description requirement. *See* OA at p. 4. The Examiner alleges that the specification does not reasonably convey to those of ordinary skill in the art that the inventors had possession of the claimed invention at the time the application was filed. *Id.* The Examiner states that the specification and claims as originally filed fail to provide clear

written description for the newly added limitations. In response, Applicants respectfully directs the Examiner's attention to the table below enumerating the explicit references in the specification supporting the claim language questioned by the Examiner. Applicants believe after Examiner's consideration of the table below, it would become clear that the original specification and claims as filed fully support and further convey to those of ordinary skill in the art that the inventors had full possession of the entire scope of the claims at the time this application was filed.

Nevertheless to fully address the issues raised, Applicants submit that Examiner's rejection does not follow the proper USPTO practice. Initially Applicants state that the Written Description Guidelines does not require an *ipsis verbis* disclosure or all species of opioid agonists in the Specification. The current Written Description Training Manual, Revision 1, published by the USPTO on March 28, 2008 ("Written Description Guidelines"), and the Written Description Requirements set forth in Federal Registry, 66(4):1130, Jan 5, 2001 articulate specific factors to be considered by the Examiners in imposing a rejection under 35 U.S.C. 112, first paragraph for purposes of assessing the disclosure of different species.

A proper and objective analysis in a Written Description inquiry requires consideration of such factors as: (1) actual reduction to practice, (2) disclosure of drawings or structural chemical formulas, and (3) sufficient relevant identifying characteristics, such as (a) complete structure, (b) partial structure, (c) physical and/or chemical properties, (d) functional characteristics when coupled with known or disclosed correlation between function and structure, (4) method of making the claimed invention, (5) level of skill and

knowledge in the art, and also (6) predictability in the art. *See* USPTO Written Description Guidelines at p. 1.

In the present case, the Examiner's rejection merely amounts to a general allegation that the language of the "opioid agonist" used in the claim is broad. Yet, the Examiner has not provided any such analysis showing any insufficiency in the identifying characteristics, nor has he considered any of the factors enumerated in the Written Description Guidelines. In fact, the Examiner has not provided any evidence suggesting that any specific opioid agonist would not work in the framework of the present invention. The sole statement in support of Examiner's position is that:

> the disclosure of specific species of compounds, wherein albeit some of the disclosed compounds may very well function as opioid agonist(s), fails to provide clear written support to now claim the use of any generic opioid agonist *per se* that was not previously disclosed either explicitly or implicitly, by the specification or claim as originally filed.

See OA at p. 5, 1st paragraph. Such statement does not satisfy Examiner's burden of proof for non-possession of the invention.

What the Examiner has failed to appreciate is that at least one essential feature of the present application is that the present formulations provide an alternative approach for preventing potential abuse of opioid agonists. The Examiner simply ignores the teachings that the current invention hinges on mixing an opioid agonist with a polymer to create a formulation, wherein the opioid agonist can not be separated from the polymeric matrix. Therefore, the Examiner's ruling based on the explicit reciting of the term "agonist" or disclosure of a specific number of species is improper and without legal and scientific merits.

Applicants respectfully submit that all that is required to satisfy the written description requirement of section 112 is whether one skilled in the art can reasonably conclude that the inventor was in possession of the claimed method at the time the application was filed, not *ipsis verbis* disclosure of all known information in the Specifications concerning all species of opioid agonists or an explicit recitation of the term. Applicants submit that the present Specification clearly discloses the inventive concepts and further reduces the invention to practice by the way of working examples to the extent necessary to show possession.

Furthermore, a competent factual analysis of the relevant factors articulated in the written description guidelines would prove that the Specification sufficiently provide the inventive characteristics. Addressing these factors, Applicants have met and will again demonstrate that there is adequate evidence supporting inventors' possession of the instant invention at the time the application was filed:

DISCLOSURE OF A COMPLETE OR PARTIAL STRUCTURE

The disclosure of the present invention satisfies this factor. Not only does the Specification describe various types of opioid agonists; it also specifically recites the desired physical characteristics of such compounds suitable to be used within the framework of the present invention.

For example, at least 30 different opioid agonists are named to be suitable candidates as the active ingredient capable of abuse with particular interest in oxycodone. Therefore, if not completely the Specification provides at least a partial disclosure of the structure and function of the compounds of the invention.

PHYSICAL OR CHEMICAL PROPERTIES

The disclosure of the present application satisfies this factor. The Specifications describe the chemical properties of the compounds, i.e. they not only have abuse potential, but must also be water soluble. Therefore, the Specification meets such requirement.

FUNCTIONAL CHARACTERISTICS

The disclosure of the present application satisfies this factor. Opioid agonists are well known in the art as narcotic opioid medications with high abuse potential. Therefore, the disclosures for the scope of such terms are clear for those of ordinary skill in the field of pharmacotherapeutics.

STRUCTURE/FUNCTION CORRELATION

The disclosure satisfies this factor. Prior abuse of opioid compositions is well described in the art. The nature of abuse and extraction of the active ingredients are further disclosed. The instantly disclosed formulations are further exemplified not to contain any other ingredients capable of being abused. Thus, the structure and function relationship is clearly set forth.

METHODS OF MAKING THE PRODUCT

The disclosure satisfies this factor. The Specifications provided more than 20 pages describing suitable ingredients to be used in the formulation. It further exemplifies at least

one active ingredient among those recited in the specification. The constitution of the products and the process of making such products were shown in at least 4 examples. Thus, there was ample description of methods for making the presently claimed formulations.

ANY COMBINATION THEREOF

Following the discussion of previous factors, Applicants assert that contrary to Examiner's position, those of ordinary skill in the art were well in possession of the attributes shared by the members of the genus of "opioid agonist." Therefore reciting the same features was not necessary to satisfy the written description requirement. Applicants submit that any combination of the above factors and the understanding in the art would have clearly conveyed to those of ordinary skill in the art that Applicants were in possession of the claims at the time of filing the application. For such reasons, Applicant respectfully submits that the invention as claimed was in possession of the inventors at the time of the filing of the application.

The table below provides further clarifications for the objected language. Applicants believe that the presented amendments and arguments address the Examiner's concerns.

The Examiner's objected claim language	**Support in the Specification**
(1) the water soluble compound capable of abuse is an opioid agonist (claim 1),	a) for water soluble compound capable of abuse, see Specification at p. 7. ll. 7-9. b) for opioid agonist, see Specification at p. 7, line 7 – p. 8, line 15. Note that the recitation of opioid agonist has explicit support in the specification as drugs such as

	morphine, alfentanil, hydromorphone, fentanyl, oxycodone are all opioid agonists.
(2) the composition does not include an antagonist of the water soluble compound capable of abuse (claim 1),	See specification at p. 3, ll. 8-10, which states that previous prior art controlled release formulations contain an opioid antagonist to mitigate abuse. The Specification then distinguishes the present invention, which does not employ an opioid antagonist. Further, none of the presently disclosed examples contain any opioid antagonist. Thus the recitation has explicit support for the language that the claimed composition contains no antagonist of the water soluble compound, i.e. opioid agonists.
(3) the viscoelastic polymer in non-erodible at pH less than about 6 or is erodible in the presence of bile salts and lipase (claims 4-5),	Claim 7 has been deleted to resolve this issue.
(4) viscoelastic polymer is a triglyceride wax selected from the group consisting of a hydrogenated cottonseed oil wax, partially hydrogenated soybean oil, carnauba wax or mixture thereof (claim 40)	Claim 40 has been amended to remove the disputed language.

IV. REJECTION OF CLAIMS UNDER 35 U.S.C. § 112 SECOND PARAGRAPH IS NOW MOOT.

The Examiner has rejected claims 7 and 24 respectively for the recitation of the term narcotic analgesic. Claim 7 has been deleted and claim 24 now refers to opioid agonists. For such reasons the rejection should now be withdrawn.

V. REJECTION OF CLAIMS 1, 9, 11, 24, 40 UNDER 35 U.S.C. § 103(A) SHOULD BE WITHDRAWN BECAUSE THE PRIOR ART FAILS TO MEET ALL THE ELEMENTS OF THE PRESENTED CLAIMS.

A. *Cain fails to teach all the structural limitations of the claims*

The Examiner rejected claims 1, 9, 11, 24, 40 as being obvious over Cain et al., US Patent 3,402,240. Applicants respectfully traverse because Cain fails to meet all the elements of the present claims.

Initially, Applicant states that the Examiner has completely ignored at least two structural limitations expressly recited in present claim 1. First, the present claim 1 requires particles of a water soluble compound, and further that each particle is wetted with a coating of the matrix material. This element has not been described by Cain. In fact, there is no discussion or analysis provided by the Examiner as how Cain meets or fairly suggests such structural feature.

The second structural limitation that the Examiner has failed to appreciate is that the composition comprises a plurality of microspheres and each of these micropsheres has the composition set forth in (i) and (ii) of claim 1. Again, the Examiner has failed to provide any analysis or any rational as to how Cain has described or suggested this limitation. In fact, there is no discussion as to how Cain meets or fairly suggests this claimed structural feature. For at least these reasons, the rejection fails to set forth a *prima facia* case for obviousness.

B. *The formulations of prior art can not and do not suggest the properties of the present claims.*

Having not met such structural limitation, the Examiner goes on to allege that the "teaching of a composition with identical formulation components and characteristics must necessarily possess the same functional properties." *See* OA at p. 10. Applicants respectfully

submit that the present invention hinges on the unexpected discovery that the components of the present formulation can not be isolated. This discovery is a critical concept as to provide an abusive resistant formulation of an opioid agonist. Cain has neither foreseen nor suggested any modifications to achieve such characteristics.

Applicants submit that the Supreme Court has articulated that "a patent composed of several elements is not proved obvious merely by demonstrating that each of its elements was, independently, known in the prior art." *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. 398, 418 (2007). In fact, for the obviousness analysis, the Court looks for "a reason that would have prompted a person of ordinary skill in the relevant field to combine the elements in the way the claimed new invention does..." *Id.* at 418-419. Thus, the Court acknowledged the importance of providing a rationale for practicing the claimed subject matter when it concluded that a rejection for obviousness must include "articulated reasoning with some rational underpinning to support the legal conclusion." *KSR Int'l Co. v. Teleflex Inc.,* 550 U.S. 398, 418 (2007), quoting *In re Kahn*, 441 F.3d 977, 988 (Fed. Cir. 2006).

Here, all that has been provided by the Examiner is "a paradigm of trial and error," which does not meet the standard for a *prima facia* case of obviousness. *Sanofi et al v. Apotex*, 550 F.3d 1075 (Fed. Cir. 2008). There is simply no predictability in the art as to whether one, following the teachings of Cain could or would have provided a reasonable expectation that the composition of the instant invention can be made.

Applicants further add that Examiner's conclusion is not supported by any of the legal precedents cited at pages 11-12 of the OA. None of the cited references provide a factual scenario similar to those of the present case. Thus, the rejection not only fails to meet

all the limitations of the present claims, but also fails to provide any motivation in the art to modify the teachings of Cain to reach the present claims.

CONCLUSION

In view of these remarks, applicants believe that this application is in a condition for allowance and an early notice to this effect is earnestly solicited. If the Examiner does not believe that such action can be taken at this time or if the Examiner feels that a telephone interview is necessary or desirable, applicant welcomes the Examiner to call the undersigned at 609-844-3030.

The USPTO is authorized to charge Deposit Account No. 50-1943 for any charges in connection with this matter.

Respectfully submitted,

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